Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Oct-2024
Document Type: USP Monographs
DocId: GUID-B0134B47-2271-40C1-BA6D-62C4FB353B70_2_en-US
DOI: https://doi.org/10.31003/USPNF_M3171_02_01
DOI Ref: uwcl7

Cetirizine Hydrochloride Tablets

DEFINITION
Cetirizine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$).

IDENTIFICATION
• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
• **Procedure**

Solution A: 2 N sulfuric acid and water (2:33)

Buffer: 2.9 mL/L of phosphoric acid in water

Mobile phase: Acetonitrile and *Buffer* (3:7)

Diluent: Acetonitrile, *Solution A*, and water (100:1:100)

Standard solution: 0.2 mg/mL of USP Cetirizine Hydrochloride RS in *Diluent*

Sample solution: 0.2 mg/mL of cetirizine hydrochloride in *Diluent* from NLT 20 powdered Tablets. [Note—Sonicate, if necessary.]

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

Run time: 1.3 times the retention time of cetirizine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Cetirizine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of cetirizine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS
• **Dissolution ⟨711⟩**

Test 1

Medium: Water; 900 mL, degassed

Apparatus 2: 50 rpm

Time: 30 min

Buffer: 2.9 mL/L of phosphoric acid in water

Mobile phase: Acetonitrile and *Buffer* (2:3)

Standard solution: 11 µg/mL of USP Cetirizine Hydrochloride RS in water. This solution can be stored for 48 h at room temperature.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 50 µL

Run time: 1.3 times the retention time of cetirizine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S/L) \times V \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Cetirizine Hydrochloride RS in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium,* 900 mL

Tolerances: NLT 80% (*Q*) of the labeled amount of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: Water; 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Buffer: 0.4 g/L of 1-heptane sulfonic acid sodium salt

Mobile phase: Acetonitrile and *Buffer* (50:50). Adjust with 0.1 N sulfuric acid to a pH of 3.5.

Standard solution: 11 µg/mL of USP Cetirizine Hydrochloride RS in *Medium*

Sample solution: Pass a 20-mL portion of the solution under test through a nylon filter of 0.45-µm pore size. Discard the first 10 mL of the filtrate.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 210 nm

Column: 3.9-mm × 30-cm; 10-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 50 µL

Run time: 1.6 times the retention time of cetirizine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S/L) \times V \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Cetirizine Hydrochloride RS in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium,* 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) is dissolved.

Test 3: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: (L/900) mg/mL of USP Cetirizine Hydrochloride RS in water, where L is the label claim of cetirizine hydrochloride, in mg/Tablet

Sample solution: Centrifuge a portion of the solution under test for NLT 15 min at 3000 rpm.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

Analytical wavelength: UV 231 nm

Blank: *Medium*

Path length: 1 cm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Cetirizine Hydrochloride RS in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

IMPURITIES

Change to read:

• **Organic Impurities**

Solution A: 2 N sulfuric acid and water (2:33)

Buffer: 3.4 g/L of ▲tetrabutylammonium▲ (ERR 1-Oct-2024) hydrogen sulfate in water

Diluent: Acetonitrile, *Solution A*, and water (910:27:63)

Mobile phase: Acetonitrile, *Solution A*, and *Buffer* (93:5:2)

Standard solution: 1.5 µg/mL of USP Cetirizine Hydrochloride RS in *Diluent*

Sample solution: 0.5 mg/mL of cetirizine hydrochloride in *Diluent* from NLT 20 powdered Tablets. [Note—Sonicate, if necessary.]

Chromatographic system

(See *Chromatography* ⟨621⟩*, System Suitability*.)

Mode: LC

Detector: UV 230 nm

Column: 4.0-mm × 25-cm; 5-µm packing L3

Flow rate: 0.8 mL/min

Injection volume: 20 µL

Run time: 2.5 times the retention time of cetirizine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 10.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of cetirizine from the *Standard solution*

C_S = concentration of USP Cetirizine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of cetirizine hydrochloride in the *Sample solution* (mg/mL)

F = relative response factor (see *Table 1*)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Cetirizine lactose ester[a]	0.56	1.0	0.5
Cetirizine	1.0	—	—
Cetirizine ethanol[b]	1.67	1.2	0.4
Any unspecified degradation product	—	—	0.2
Total impurities	—	—	1

[a] 6-*O*-[2-(2-{4-[(4-Chlorophenyl)(phenyl)methyl]piperazin-1-yl}ethoxy)acetyl]-β-D-galactopyranosyl-(1→4)β-D-glucopyranose.

[b] 2-[4-[(4-Chlorophenyl)phenylmethyl]piperazin-1-yl]ethanol.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, and store below 30°.
- **Labeling:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP Reference Standards** ⟨11⟩
  USP Cetirizine Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CETIRIZINE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 36(2)

Current DocID: GUID-B0134B47-2271-40C1-BA6D-62C4FB353B70_2_en-US

DOI: https://doi.org/10.31003/USPNF_M3171_02_01

DOI ref: uwcl7